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 Novartis Vaccines and Diagnostics, Inc.

UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF NEW YORK

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|---------------------------------------|-------|-----------------------|--|
| | ----- | x | |
| DR. ANTHONY CERAMI, | : | 1:07-CV-05634-AKH-DFE | |
| | : | | |
| Plaintiff, | : | <u>ANSWER</u> | |
| | : | | |
| -against- | : | | |
| | : | | |
| NOVARTIS AG and NOVARTIS VACCINES AND | : | | |
| DIAGNOSTICS, INC., | : | ECF CASE | |
| | : | | |
| Defendants. | : | | |
| | : | | |
| ----- | | x | |

Defendant Novartis Vaccines and Diagnostics, Inc. (“V&D”), by its attorneys Morrison & Foerster LLP, answers the Complaint of plaintiff Dr. Anthony Cerami (“Cerami”), dated June 13, 2007, in the above-captioned action (the “Complaint”) as follows:

With regards to the allegations set forth in the first unnumbered paragraph under the heading “NATURE OF THE ACTION,” V&D denies knowledge or information sufficient to form a belief as to the truth of the allegations, except admits on information and belief that Cerami directed the research activities of a laboratory at The Rockefeller University in 1981 and that he made discoveries that led to the issuance of patents.

With regards to the allegations set forth in the second unnumbered paragraph under the heading “NATURE OF THE ACTION,” V&D denies the allegations, except (1) admits that it is an indirect, wholly-owned subsidiary of Novartis AG, that it entered into a license agreement

with The Rockefeller University in June 1985, that Cerami agreed to be a consultant and advisor to V&D on or about August 21, 1985, and that the Complaint purports to assert certain rights against and seek certain relief with respect to V&D, and (2) respectfully refers the Court to the Complaint, and Exhibits A and B thereto for their contents.

1. Admits that Cerami is a biochemist, a member of the National Academy of Sciences and is a named inventor on numerous patents and an author on numerous scientific publications, and, on information and belief, that he is an individual residing in and a citizen of the State of New York. Denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 1 of the Complaint.

2. Denies the allegations in Paragraph 2 of the Complaint, except admits that Novartis AG is a corporation organized and existing under the laws of Switzerland, with its principal place of business in Basel, Switzerland, that V&D is an indirect, wholly-owned subsidiary of Novartis AG, and that V&D and Novartis AG are engaged in the manufacture and sale of pharmaceuticals, vaccines and other products.

3. Denies the allegations in Paragraph 3 of the Complaint, except admits that it is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in Emeryville, California, that it is an indirect, wholly-owned subsidiary of Novartis AG, that it develops, manufactures, and sells vaccines and other products, and that on April 19, 2006, Chiron Corporation filed a Certificate of Merger, pursuant to which Novartis Biotech Partnership, Inc. was merged with and into Chiron Corporation, with Chiron Corporation as the surviving entity, and that after the merger became effective on April 20, 2006, Chiron Corporation changed its name to Novartis Vaccines and Diagnostics, Inc. Chiron Corporation and Novartis Vaccines and Diagnostics, Inc. are each referred to herein as "V&D."

4. The allegations of Paragraph 4 of the Complaint are legal conclusions to which no response is required and respectfully refers the Court to the Complaint for its contents.

5. The allegations of Paragraph 5 of the Complaint are legal conclusions to which no response is required, except admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332.

6. The allegations of Paragraph 6 of the Complaint are legal conclusions to which no response is required, but admits that venue is appropriate in this Court pursuant to 28 U.S.C. § 1391.

7. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7 of the Complaint, except admits on information and belief that Cerami directed the research activities of the Laboratory of Medical Biochemistry at The Rockefeller University in the late 1970's, that this laboratory undertook research regarding a phenomenon that Dr. Cerami had observed while working in Africa, which research resulted in inventions that were the subjects of patent applications, including a patent application filed in 1981.

8. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 of the Complaint, except admits on information and belief that Cerami operated under an intellectual property policy of The Rockefeller University.

9. Admits the allegations of Paragraph 9 of the Complaint.

10. Denies the allegations of Paragraph 10 of the Complaint and refers the Court to the `932, `290, and `098 applications and the "Ward Opinion" for their contents.

11. Denies the allegations of Paragraph 11 of the Complaint and refers the Court to Exhibit A to the Complaint for its contents.

12. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of the Complaint.

13. Denies the allegations of Paragraph 13 of the Complaint.

14. Denies the allegations of Paragraph 14 of the Complaint, except admits that V&D negotiated separately with Cerami for Cerami to act as a consultant and advisor to V&D in the field of mammalian cell expression.

15. Denies the allegations of Paragraph 15 of the Complaint, except admits that Cerami agreed to be a consultant and advisor to V&D on or about August 21, 1985.

16. Denies the allegations of Paragraph 16 of the Complaint.

17. Denies knowledge or information sufficient to form a belief as to the truth of the allegations that “[o]ver the two decades following the August 1985 Agreement, Dr. Cerami and others discovered more about the properties of TNF and the benefits of the antibodies.” Denies the remaining allegations of Paragraph 17 of the Complaint, except admits that U.S. Patent Nos. 6,309,640 and 6,419,927 issued in 2001 and 2002 and claim back to the `932 application filed in 1981, that Cerami and Masanobu Kawakami are listed as inventors on the `640 and `927 patents, that those patents were assigned to The Rockefeller University, and that V&D holds a license to them through the license agreement attached to the Complaint as Exhibit A.

18. Denies the allegations of Paragraph 18 of the Complaint.

19. Denies knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 19 of the Complaint, except admits that the product identified in subparagraph a. was approved by the FDA, that the product identified in subparagraph b. was approved by the FDA, and that publicly reported sales of the products identified in subparagraph c. exceeded \$3.5 billion in 2006.

20. Denies knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 20 of the Complaint.

21. Denies the allegations of Paragraph 21 of the Complaint.

22. Denies the allegations of Paragraph 22 of the Complaint, and avers that on April 28, 2004, V&D and The Rockefeller University filed their complaint in *The Rockefeller University et al. v. Centocor, Inc. et al.*, Civ. Action No. 2:04-cv-168 (TJW), which complaint identified the products identified in Paragraph 22 of the Complaint, and charged Centocor and Abbott with infringement of patents that issued in 2001 and 2002.

23. Denies the allegations of Paragraph 23 of the Complaint, except admits that Judge Ward held a *Markman* hearing and that he issued a *Markman* order in *The Rockefeller University et al. v. Centocor, Inc. et al.*, Civ. Action No. 2:04-cv-168 (TJW), on October 3, 2005.

24. Denies the allegations of Paragraph 24 of the Complaint, except admits that V&D, The Rockefeller University, and Centocor, Inc. entered into a confidential settlement agreement after October 3, 2005.

25. Denies the allegations of Paragraph 25 of the Complaint, except admits that The Rockefeller University and V&D settled with Abbott Laboratories after settling with Centocor, Inc., and that pursuant to that settlement agreement The Rockefeller University, V&D, and Abbott Laboratories agreed to dismiss the pending patent litigation and to submit their dispute to binding arbitration, and that the arbitration hearing commenced in late 2006, and avers that the arbitration proceeding is subject to confidentiality agreements.

26. Denies knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 26 of the Complaint, except admits that the award in the arbitration was issued in early 2007 and avers that the arbitration is subject to confidentiality agreements.

27. Denies the allegations of Paragraph 27 of the Complaint, except admits that the dispositions of *The Rockefeller University et al. v. Centocor, Inc. et al.*, Civ. Action No. 2:04-cv-168 (TJW), and of the above-referenced arbitration are the subject of confidentiality agreements.

28. Denies the allegations of Paragraph 28 of the Complaint.

29. Denies the allegations of Paragraph 29 of the Complaint, except admits on information and belief that Cerami has received amounts from The Rockefeller University based on payments shared by The Rockefeller University and V&D.

FIRST CLAIM FOR RELIEF

30. The allegations of Paragraph 30 of the Complaint are legal conclusions to which no response is required; to the extent that a response is required, denies the allegations of Paragraph 30 of the Complaint.

31. The allegations of Paragraph 31 of the Complaint are legal conclusions to which no response is required; to the extent that a response is required, denies the allegations of Paragraph 31 of the Complaint.

32. The allegations of Paragraph 32 of the Complaint are legal conclusions to which no response is required; to the extent that a response is required, denies the allegations of Paragraph 32 of the Complaint, except admits that publicly reported sales of the products identified in Paragraph 32 of the Complaint exceeded \$3.5 billion in 2006.

SECOND CLAIM FOR RELIEF IN THE ALTERNATIVE

33. In response to the allegations in Paragraph 33 of the Complaint, repeats and realleges each and every response to Paragraphs 1 through 32 of the Complaint, as if fully set forth herein.

34. Denies the allegations of Paragraph 34 of the Complaint, and avers that to the extent Cerami provided services to V&D, V&D has fully compensated Cerami for such services.

35. The allegations of Paragraph 35 of the Complaint are legal conclusions to which no response is required; to the extent that a response is required, denies the allegations of Paragraph 35 of the Complaint.

36. Denies the allegations of Paragraph 36 of the Complaint.

37. The allegations of Paragraph 37 of the Complaint are legal conclusions to which no response is required; to the extent that a response is required, denies the allegations of Paragraph 37 of the Complaint.

38. Denies the allegations of Paragraph 38 of the Complaint.

39. The allegations of Paragraph 39 of the Complaint are legal conclusions to which no response is required; to the extent that a response is required, denies the allegations of Paragraph 39 of the Complaint.

40. The allegations of Paragraph 40 of the Complaint are legal conclusions to which no response is required; to the extent that a response is required, denies the allegations of Paragraph 40 of the Complaint.

41. The allegations of Paragraph 41 of the Complaint are legal conclusions to which no response is required; to the extent that a response is required, denies the allegations of Paragraph 41 of the Complaint.

THIRD CLAIM FOR RELIEF

42. In response to the allegations in Paragraph 42 of the Complaint, repeats and realleges each and every response to Paragraphs 1 through 41 of the Complaint, as if fully set forth herein.

43. The allegations of Paragraph 43 of the Complaint are legal conclusions to which no response is required; to the extent that a response is required, denies the allegations of Paragraph 43 of the Complaint.

44. Denies knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 44 of the Complaint.

45. The allegations of Paragraph 45 of the Complaint are legal conclusions to which no response is required; to the extent that a response is required, denies the allegations of Paragraph 45 of the Complaint.

46. The allegations of Paragraph 46 of the Complaint are legal conclusions to which no response is required; to the extent that a response is required, denies the allegations of Paragraph 46 of the Complaint.

AFFIRMATIVE DEFENSES

47. As and for its affirmative defenses, V&D alleges as follows, without assuming any burden of pleading or proof that would otherwise rest with Cerami:

FIRST AFFIRMATIVE DEFENSE

48. The Complaint fails, in whole or in part, to state a claim against V&D upon relief may be granted.

SECOND AFFIRMATIVE DEFENSE

49. The Complaint is uncertain and ambiguous.

THIRD AFFIRMATIVE DEFENSE

50. The “August 1985 Agreement” (also referred to as the “Consulting Agreement”) is too indefinite to constitute an enforceable contract.

FOURTH AFFIRMATIVE DEFENSE

51. The “August 1985 Agreement” (also referred to as the “Consulting Agreement”) is unenforceable and cannot constitute an existing contractual relation due to the fact it contemplated a future meeting of the minds on essential terms, and thus was merely an unenforceable “agreement to agree.”

FIFTH AFFIRMATIVE DEFENSE

52. Cerami's claims based on the "August 1985 Agreement" (also referred to as the "Consulting Agreement") are barred by the Statute of Frauds.

SIXTH AFFIRMATIVE DEFENSE

53. The "August 1985 Agreement" (also referred to as the "Consulting Agreement") is void and unenforceable as against public policy.

SEVENTH AFFIRMATIVE DEFENSE

54. V&D has fully performed any and all contractual and equitable duties, and fully performed all actions required under its agreements, if any, with Cerami.

EIGHTH AFFIRMATIVE DEFENSE

55. Cerami's claim for unjust enrichment is barred by the existence of a valid and enforceable contract.

NINTH AFFIRMATIVE DEFENSE

56. Cerami's claim for unjust enrichment is barred to the extent that it is based on future events.

TENTH AFFIRMATIVE DEFENSE

57. Cerami's claim for unjust enrichment is barred as against public policy.

ELEVENTH AFFIRMATIVE DEFENSE

58. Any injuries incurred or damages suffered, as alleged in the Complaint, were caused or contributed to by Cerami's own conduct, and not by any conduct of V&D.

TWELFTH AFFIRMATIVE DEFENSE

59. Cerami's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, estoppel, and unclean hands.

THIRTEENTH AFFIRMATIVE DEFENSE

60. Cerami's claims are barred, in whole or in part, because of a lack of irreparable injury.

FOURTEENTH AFFIRMATIVE DEFENSE

61. Some or all of Cerami's claims against V&D are non-justiciable and/or otherwise not ripe for adjudication.

FIFTEENTH AFFIRMATIVE DEFENSE

62. Cerami has failed to show the lack of an adequate remedy at law.

SIXTEENTH AFFIRMATIVE DEFENSE

63. V&D reserves the right to plead additional affirmative defenses as discovery progresses.

WHEREFORE, V&D demands judgment as follows:

- A. That judgment be entered in favor of V&D and against Cerami;
- B. That the Complaint be dismissed with prejudice;
- C. That V&D be awarded its costs of suit herein incurred;
- D. That V&D be awarded its expenses, including reasonable attorneys' fees; and
- E. For such other and further relief as the Court may deem just and proper.

Dated: New York, NY
August 13, 2007

MORRISON & FOERSTER LLP

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